

EXHIBIT 3



APPROVED DRUG PRODUCTS

WITH

**THERAPEUTIC
EQUIVALENCE
EVALUATIONS**

44th EDITION

**THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER
SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY**

2024

APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2023.

44th EDITION



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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2024

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVED DRUG PRODUCTS
with
Therapeutic Equivalence Evaluations**

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2.0 HOW TO USE THE DRUG PRODUCT LISTS

2.1 Key Sections for Using the Drug Product Lists

This publication contains illustrations, along with Drug Product Lists, indices, and lists of abbreviations and terms which facilitate their use.

Illustrations. The annotated *Drug Product Illustration* (see Section 2.2) and the *Therapeutic Equivalence Evaluations Illustration* (see Section 2.3) are offered to provide further clarification. These depict the format found in the Prescription Drug Product List (the only list in which therapeutic equivalence evaluation codes are displayed).

Drug Product Lists. The Prescription and OTC Drug Product Lists, arranged alphabetically by active ingredient(s), contain product identification information (active ingredients, dosage forms, routes of administration, product names, applicants, strengths) for single and multiple ingredient drug products. Also shown are the application number and drug product number (FDA internal computer data use only) and approval dates for those drug products approved on or after January 1, 1982. The application number preceded by "N" is a New Drug Application (NDA or commonly the innovator). The application number preceded by an "A" is an Abbreviated New Drug Application (ANDA or commonly the generic).

The Discontinued Drug Product List, arranged alphabetically by active ingredient(s), contains product identification information (active ingredients, dosage forms, routes of administration, product names, applicants, strengths).

If a prescription drug product is available from more than one source (multisource), a therapeutic equivalence code will appear in front of the applicant's name. If a product is therapeutically equivalent to one or more products or to an appropriate reference, it will be designated with a code beginning with "A" and the entry will be underlined and printed in bold font for emphasis.

Active ingredient headings for multiple ingredient (combination) drug products are arranged alphabetically. For purposes of this publication, this alphabetical sort takes precedence over United States Pharmacopeia official monograph order (i.e., Reserpine, Hydralazine Hydrochloride, Hydrochlorothiazide). For example, product information labeled as Reserpine, Hydrochlorothiazide and Hydralazine Hydrochloride appears under the active ingredient heading *Hydralazine Hydrochloride; Hydrochlorothiazide; Reserpine*. A cross-reference to the product information (for prescription and OTC products) appears for each additional active ingredient in the product. For combination drug products, the ingredient strengths are separated by semicolons and appear in the same relative sequence as the ingredients in the heading. Available strengths of the dosage form from an applicant appear on separate lines.

To use the Drug Product Lists, determine by alphabetical order the ingredient under which the product information is listed, using the Product Name Index, if necessary. Then, find the ingredient in the applicable Drug Product List. Proceed to the dosage form and route of administration and

compare products within that ingredient heading only. Therapeutic equivalence or inequivalence for prescription products is determined on the basis of the therapeutic equivalence codes provided within that specific dosage form and route heading. The OTC Drug Product List, Discontinued Drug Product List, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List have their data arranged similarly.

The Discontinued Drug Product List contains approved products that have never been marketed, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, are for military use, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing. All products having a "@" in the December Cumulative Supplement of the previous Edition List have been added to the Discontinued Drug Product List appearing in this Edition. In addition, approved drug products that are not in the commercial distribution channel e.g., approved drug products in applications for export only are also listed in the Discontinued Drug Product List.

Product Name Index (*Prescription and OTC Drug Product Lists*). This is an index of drug products by trade name or established name of the active ingredient, if no trade name exists. The second term of each entry indicates the active ingredient name under which product information can be found in the appropriate Drug Product List. For those drug products with multiple active ingredients, only the first active ingredient (in alphabetical order) will appear. OTC products are so designated.

Product Name Index Listed by Applicant (*Prescription and OTC Drug Product Lists*). This is an index that cross-references applicants to drug products. The bolded and underlined entry represents the applicant name abbreviation used in this publication. Each complete applicant name that is represented by the abbreviated name is marked with an asterisk (*). Listed under each complete applicant name is the first alphabetically arranged ingredient under which product information can be found in the appropriate Drug Product List.

OTC products are so designated. To use the Drug Product Lists, determine by alphabetical order the ingredient under which the product information is listed, using the Product Name Index, if appropriate.

Uniform Terms. To improve readability, uniform terms are used to designate dosage forms, routes of administration, and abbreviations used to express strengths. These terms are listed in Appendix C. In some cases, the terms used may differ from those used in product labels and other labeling.

2.2 DRUG PRODUCT ILLUSTRATION

ACTIVE INGREDIENT	→	<u>PERIDINE HYDROCHLORIDE</u>									
DOSAGE FORM	→	INJECTABLE INJECTION									
TRADE OR GENERIC NAMES	→	<u>A</u>									
REFERENCE LISTED DRUG * ()	→	<u>A</u>	PARKE-DAVIS								AU 22, 1983
REFERENCE STANDARD * ()	→	<u>A</u>									AU 22, 1983
	→	<u>A</u>									AU 22, 1983
	→	<u>A</u>									JAN 01, 1989
THERAPEUTIC EQUIVALENCE (TE)	→	<u>A</u>	PARKE-DAVIS			<u>A</u>				001	FEB 29, 1983
CODE FOR ULTISOURCE PRODUCT	→	<u>A</u>				<u>A</u>				002	FEB 29, 1983
	→	<u>A</u>				<u>A</u>				003	FEB 29, 1983
	→	<u>A</u>				<u>A</u>				00	MAR 08, 1992
SINGLE SOURCE PRODUCT (NO TE CODE)	→	<u>A</u>	TEO I LLC	10	L	A099225	001				DEC 12, 1995
	→		JOHNSON & JOHNSON			<u>A</u>					NOV 02, 1993
	→		ENDRA PHARM	150	L	A09	001				OCT 31, 1999
APPLICANT	→										
AVAILABLE STRENGTH(S) OF A PRODUCT	→										
APPLICATION NUMBER	→										
PRODUCT NUMBER IS FOR FDA INTERNAL COMPUTER DATA USE ONLY	→										
APPROVAL DATE	→										

*NOTE REFERENCE LISTED DRUG AND REFERENCE STANDARD ARE DISCUSSED IN THE PREFACE SECTION 1.

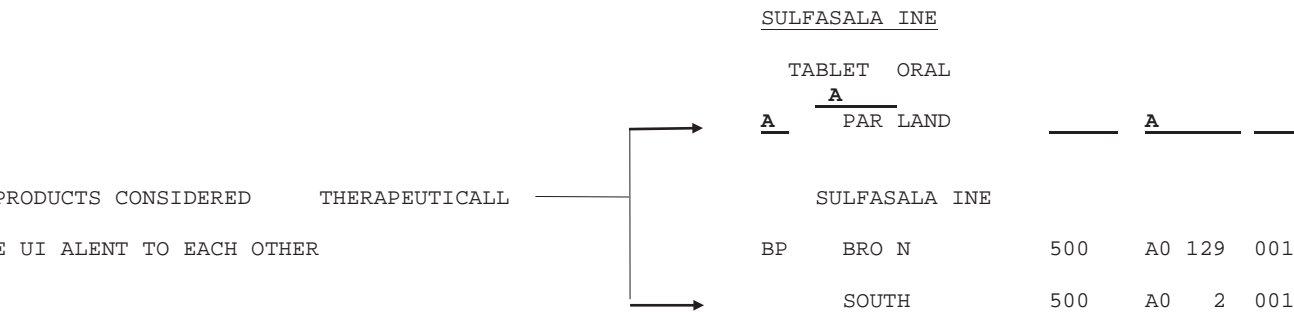
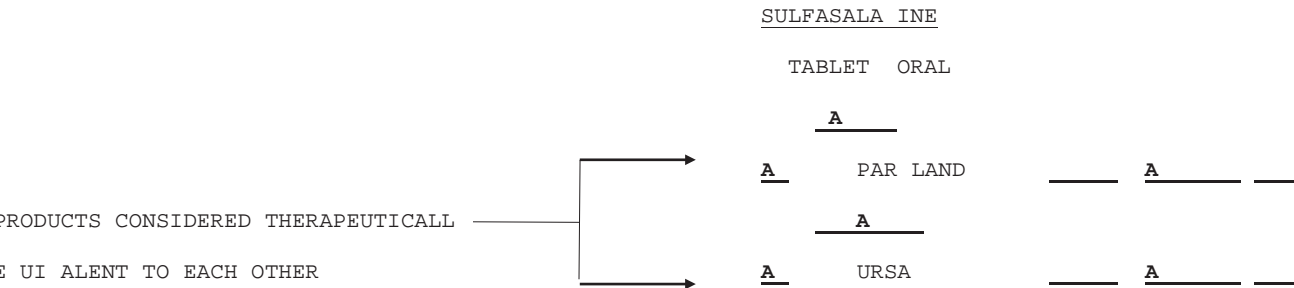
A

ALPHABETICALLY SORTED BY	→	<u>PERIDINE HYDROCHLORIDE PERIDINE HYDROCHLOROTHIAZIDE RESERPINE</u>									
PRODUCT INFORMATION	→	TABLET ORAL PERIDINE HYDROCHLOROTHIAZIDE, RESERPINE AND PERIDINE HYDROCHLORIDE HCL REINOLD LABS 25 15 0.1 A09808 001 JAN 18, 1982									

THIS EXAMPLE IS FOR PURPOSE OF ILLUSTRATION ONLY. IT DOES NOT REPRESENT ACTUAL PRODUCTS FROM THE PRESCRIPTION DRUG PRODUCT LIST.

2. THERAPEUTIC EQUIVALENCY ILLUSTRATION

DRUG PRODUCTS CODED **A** (OR AN CODE BE INNIN ITH AN **A**) UNDER AN IN REDIENT AND DOSAGE FORM HEADLINE ARE CONSIDERED THERAPEUTICALLY EQUIVALENT ONLY TO OTHER PRODUCTS CODED **A** (OR AN CODE BE INNIN ITH AN **A** AND TO THOSE CODED (OR AN CODE BE INNIN ITH) AND AN PRODUCTS NOT LISTED. DRUG PRODUCTS CODED (OR AN CODE BE INNIN ITH A) ARE CONSIDERED THERAPEUTICALLY EQUIVALENT TO AN OTHER PRODUCT. FOR A COMPLETE EXPLANATION OF THE CODES REFER TO SECTION 1. OF THE INTRODUCTION



NOTE BOLD FONT AND UNDERLINING DENOTES ULTISOURCE PRODUCTS WHICH ARE CONSIDERED THERAPEUTICALLY EQUIVALENT.

THIS EXAMPLE IS FOR PURPOSES OF ILLUSTRATION ONLY. IT DOES NOT REPRESENT ACTUAL PRODUCTS FROM THE PRESCRIPTION DRUG PRODUCT LIST.

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PRESCRIPTION DRUG PRODUCT LIST

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ADAPALENE

SOLUTION; TOPICAL

ADAPALENE

<u>AB</u>	CALL INC	<u>0.1%</u>	<u>A203981</u>	<u>001</u>	Sep 23, 2016
<u>AB</u>		<u>0.1%</u>	<u>A204593</u>	<u>001</u>	Jan 05, 2016

ADAPALENE; BENZOYL PEROXIDE

GEL; TOPICAL

ADAPALENE AND BENZOYL PEROXIDE

<u>AB</u>	ACTAVIS LABS UT INC	<u>0.3%;2.5%</u>	<u>A209641</u>	<u>001</u>	Jun 22, 2022
<u>AB</u>	ALEMBIC	<u>0.3%;2.5%</u>	<u>A214185</u>	<u>001</u>	Aug 04, 2022
<u>AB</u>	ENCUBE	<u>0.1%;2.5%</u>	<u>A206164</u>	<u>001</u>	May 23, 2018
<u>AB</u>	GLENMARK PHARMS LTD	<u>0.1%;2.5%</u>	<u>A208108</u>	<u>001</u>	Nov 08, 2019
<u>AB</u>	PADAGIS ISRAEL	<u>0.1%;2.5%</u>	<u>A205033</u>	<u>001</u>	Jan 23, 2018
<u>AB</u>		<u>0.3%;2.5%</u>	<u>A212464</u>	<u>001</u>	May 31, 2022
<u>AB</u>	TARO	<u>0.1%;2.5%</u>	<u>A206959</u>	<u>001</u>	Jan 24, 2018
<u>AB</u>		<u>0.3%;2.5%</u>	<u>A209148</u>	<u>001</u>	Oct 17, 2018
<u>AB</u>	ZYDUS PHARMS	<u>0.3%;2.5%</u>	<u>A214553</u>	<u>001</u>	Jun 03, 2022

EPIDUO

<u>AB</u>	<u>+</u> !	GALDERMA LABS LP	<u>0.1%;2.5%</u>	<u>N022320</u>	<u>001</u>	Dec 08, 2008
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EPIDUO FORTE

<u>AB</u>	<u>+</u> !	GALDERMA LABS	<u>0.3%;2.5%</u>	<u>N207917</u>	<u>001</u>	Jul 15, 2015
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ADAPALENE; BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL; TOPICAL

CABTREO

<u>+</u> !	BAUSCH	0.15%;3.1%;1.2%	N216632	001	Oct 20, 2023
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ADEFOVIR DIPIVOXIL

TABLET; ORAL

ADEFOVIR DIPIVOXIL

<u>AB</u>	APOTEX	<u>10MG</u>	<u>A205459</u>	<u>001</u>	Jul 06, 2018
<u>AB</u>	SIGMAPHARM LABS LLC	<u>10MG</u>	<u>A202051</u>	<u>001</u>	Aug 29, 2013

HEPSERA

<u>AB</u>	<u>+</u> !	GILEAD	<u>10MG</u>	<u>N021449</u>	<u>001</u>	Sep 20, 2002
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ADENOSINE

INJECTABLE; INJECTION

ADENOSINE

<u>AP</u>	FRESENIUS KABI USA	<u>3MG/ML</u>	<u>A077133</u>	<u>001</u>	Apr 27, 2005	
<u>AP</u>		<u>3MG/ML</u>	<u>A205568</u>	<u>001</u>	Apr 16, 2018	
<u>AP</u>	GLAND PHARMA LTD	<u>3MG/ML</u>	<u>A077283</u>	<u>001</u>	Jun 14, 2007	
<u>AP</u>		<u>3MG/ML</u>	<u>A206778</u>	<u>001</u>	Feb 16, 2018	
<u>AP</u>	HIKMA	<u>3MG/ML</u>	<u>A076404</u>	<u>001</u>	Jun 16, 2004	
<u>AP</u>		<u>3MG/ML</u>	<u>A076500</u>	<u>001</u>	Jun 16, 2004	
<u>AP</u>	MYLAN LABS LTD	<u>3MG/ML</u>	<u>A078686</u>	<u>001</u>	May 13, 2009	
<u>AP</u>	<u>!</u>	RISING	<u>3MG/ML</u>	<u>A078076</u>	<u>001</u>	Oct 31, 2008

SOLUTION; INTRAVENOUS

ADENOSINE

<u>AP</u>	AVET LIFESCIENCES	<u>60MG/20ML (3MG/ML)</u>	<u>A202313</u>	<u>001</u>	Sep 15, 2014	
<u>AP</u>		<u>90MG/30ML (3MG/ML)</u>	<u>A202313</u>	<u>002</u>	Sep 15, 2014	
<u>AP</u>	EUGIA PHARMA	<u>60MG/20ML (3MG/ML)</u>	<u>A205331</u>	<u>001</u>	Nov 02, 2017	
<u>AP</u>		<u>90MG/30ML (3MG/ML)</u>	<u>A205331</u>	<u>002</u>	Nov 02, 2017	
<u>AP</u>	FRESENIUS KABI USA	<u>60MG/20ML (3MG/ML)</u>	<u>A077897</u>	<u>001</u>	Nov 27, 2017	
<u>AP</u>		<u>90MG/30ML (3MG/ML)</u>	<u>A077897</u>	<u>002</u>	Nov 27, 2017	
<u>AP</u>	HOSPIRA	<u>60MG/20ML (3MG/ML)</u>	<u>A203883</u>	<u>001</u>	Mar 24, 2014	
<u>AP</u>		<u>90MG/30ML (3MG/ML)</u>	<u>A203883</u>	<u>002</u>	Mar 24, 2014	
<u>AP</u>	<u>!</u>	MEITHEAL	<u>60MG/20ML (3MG/ML)</u>	<u>A077425</u>	<u>001</u>	Aug 29, 2013
<u>AP</u>	<u>!</u>		<u>90MG/30ML (3MG/ML)</u>	<u>A077425</u>	<u>002</u>	Aug 29, 2013
<u>AP</u>	MYLAN ASI	<u>60MG/20ML (3MG/ML)</u>	<u>A090212</u>	<u>001</u>	Mar 28, 2014	
<u>AP</u>		<u>90MG/30ML (3MG/ML)</u>	<u>A090212</u>	<u>002</u>	Mar 28, 2014	
<u>AP</u>	RISING	<u>60MG/20ML (3MG/ML)</u>	<u>A090450</u>	<u>001</u>	Oct 02, 2014	
<u>AP</u>		<u>90MG/30ML (3MG/ML)</u>	<u>A090450</u>	<u>002</u>	Oct 02, 2014	

AFAMELANOTIDE

IMPLANT; SUBCUTANEOUS

SCENESSE

<u>+</u> !	CLIVUNEL INC	16MG	N210797	001	Oct 08, 2019
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PRESCRIPTION DRUG PRODUCT LIST

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AFATINIB DIMALEATE

TABLET; ORAL

GILOTRIF

+	BOEHRINGER INGELHEIM	EQ 20MG BASE	N201292 001	Jul 12, 2013
+		EQ 30MG BASE	N201292 002	Jul 12, 2013
+		EQ 40MG BASE	N201292 003	Jul 12, 2013

AIR POLYMER-TYPE A

FOAM; INTRAUTERINE

EXEM FOAM KIT

+	GISKIT	10ML	N212279 001	Nov 07, 2019
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ALBENDAZOLE

TABLET; ORAL

ALBENDAZOLE

<u>AB</u>	ACTAVIS ELIZABETH	<u>200MG</u>	<u>A208094 001</u>	May 20, 2019
<u>AB</u>	! DR REDDYS	<u>200MG</u>	<u>A211034 001</u>	Jan 26, 2021
<u>AB</u>	EDENBRIDGE PHARMS	<u>200MG</u>	<u>A211117 001</u>	May 14, 2019
<u>AB</u>	MSN	<u>200MG</u>	<u>A213435 001</u>	Jan 21, 2021
<u>AB</u>	STRIDES PHARMA	<u>200MG</u>	<u>A210011 001</u>	Dec 07, 2018
<u>AB</u>	ZYDUS PHARMS	<u>200MG</u>	<u>A208979 001</u>	Dec 14, 2018

ALBUMIN HUMAN

INJECTABLE; INJECTION

OPTISON

+	GE HEALTHCARE	10MG/ML	N020899 001	Dec 31, 1997
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ALBUTEROL SULFATE

AEROSOL, METERED; INHALATION

ALBUTEROL SULFATE

<u>AB1</u>	CIPLA	<u>EQ 0.09MG BASE/INH</u>	<u>A209959 001</u>	Apr 08, 2020
<u>AB1</u>	SANDOZ	<u>EQ 0.09MG BASE/INH</u>	<u>A207085 001</u>	Jun 01, 2021
	<u>PROVENTIL-HFA</u>			
<u>AB1</u>	! KINDEVA	<u>EQ 0.09MG BASE/INH</u>	<u>N020503 001</u>	Aug 15, 1996
	<u>ALBUTEROL SULFATE</u>			
<u>AB2</u>	LUPIN	<u>EQ 0.09MG BASE/INH</u>	<u>A209954 001</u>	Aug 24, 2020
	<u>PROAIR HFA</u>			
<u>AB2</u>	! TEVA BRANDED PHARM	<u>EQ 0.09MG BASE/INH</u>	<u>N021457 001</u>	Oct 29, 2004
	VENTOLIN HFA			
BX	! GLAXOSMITHKLINE	EQ 0.09MG BASE/INH	N020983 001	Apr 19, 2001
	POWDER, METERED; INHALATION			
	PROAIR DIGIHALER			
	+ TEVA BRANDED PHARM	EQ 0.09MG BASE/INH	N205636 002	Dec 21, 2018
	PROAIR RESPICLICK			
	! TEVA BRANDED PHARM	EQ 0.09MG BASE/INH	N205636 001	Mar 31, 2015
	SOLUTION; INHALATION			
	<u>ALBUTEROL SULFATE</u>			
<u>AN</u>	LUOXIN AUROVITAS	<u>EQ 0.083% BASE</u>	<u>A206224 001</u>	Oct 17, 2017
<u>AN</u>	NEPHRON	<u>EQ 0.021% BASE</u>	<u>A076355 002</u>	Mar 31, 2010
<u>AN</u>	!	<u>EQ 0.042% BASE</u>	<u>A076355 001</u>	Jun 28, 2004
<u>AN</u>	!	<u>EQ 0.083% BASE</u>	<u>A074880 001</u>	Sep 17, 1997
<u>AN</u>	!	<u>EQ 0.5% BASE</u>	<u>A075664 001</u>	Jun 26, 2001
<u>AN</u>	! RITEDOSE CORP	<u>EQ 0.021% BASE</u>	<u>A214531 001</u>	Dec 28, 2021
<u>AN</u>		<u>EQ 0.042% BASE</u>	<u>A214531 002</u>	Dec 28, 2021
<u>AN</u>		<u>EQ 0.083% BASE</u>	<u>A077839 001</u>	Dec 16, 2008
<u>AN</u>	SENTISS	<u>EQ 0.5% BASE</u>	<u>A074543 001</u>	Jan 15, 1998
<u>AN</u>	SUN PHARM	<u>EQ 0.083% BASE</u>	<u>A207857 001</u>	Jul 21, 2017
<u>AN</u>	WATSON LABS	<u>EQ 0.021% BASE</u>	<u>A077772 001</u>	Sep 25, 2007
<u>AN</u>		<u>EQ 0.042% BASE</u>	<u>A077772 002</u>	Sep 25, 2007

SYRUP; ORAL

ALBUTEROL SULFATE

<u>AA</u>	AMNEAL PHARMS	<u>EQ 2MG BASE/5ML</u>	<u>A079241 001</u>	May 12, 2010
<u>AA</u>	CHARTWELL MOLECULAR	<u>EQ 2MG BASE/5ML</u>	<u>A078105 001</u>	Dec 27, 2006
<u>AA</u>	CHARTWELL RX	<u>EQ 2MG BASE/5ML</u>	<u>A077788 001</u>	Jun 26, 2007
<u>AA</u>	COSETTE	<u>EQ 2MG BASE/5ML</u>	<u>A074454 001</u>	Sep 25, 1995
<u>AA</u>	HIKMA	<u>EQ 2MG BASE/5ML</u>	<u>A074749 001</u>	Jan 30, 1998
<u>AA</u>	QUAGEN	<u>EQ 2MG BASE/5ML</u>	<u>A212197 001</u>	Sep 06, 2019
<u>AA</u>	! TEVA	<u>EQ 2MG BASE/5ML</u>	<u>A073419 001</u>	Mar 30, 1992

TABLET; ORAL

ALBUTEROL SULFATE

<u>AB</u>	AIZANT	<u>EQ 2MG BASE</u>	<u>A210948 001</u>	Mar 15, 2019
<u>AB</u>		<u>EQ 4MG BASE</u>	<u>A210948 002</u>	Mar 15, 2019
<u>AB</u>	AMNEAL PHARMS CO	<u>EQ 2MG BASE</u>	<u>A208804 001</u>	May 21, 2018
<u>AB</u>		<u>EQ 4MG BASE</u>	<u>A208804 002</u>	May 21, 2018

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PRESCRIPTION DRUG PRODUCT LIST

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ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

<u>AB</u>	DASH PHARMS NATCO	<u>EQ 2MG BASE</u>	<u>A072894</u>	<u>002</u>	Jan 17, 1991
<u>AB</u>	!	<u>EQ 4MG BASE</u>	<u>A072894</u>	<u>001</u>	Jan 17, 1991
<u>AB</u>	RISING	<u>EQ 2MG BASE</u>	<u>A207046</u>	<u>001</u>	Jun 29, 2018
<u>AB</u>		<u>EQ 4MG BASE</u>	<u>A207046</u>	<u>002</u>	Jun 29, 2018
<u>AB</u>	SUN PHARM INDUSTRIES	<u>EQ 2MG BASE</u>	<u>A072637</u>	<u>002</u>	Dec 05, 1989
<u>AB</u>		<u>EQ 4MG BASE</u>	<u>A072637</u>	<u>001</u>	Dec 05, 1989
<u>AB</u>	VIRTUS PHARM	<u>EQ 2MG BASE</u>	<u>A211397</u>	<u>001</u>	Oct 26, 2018
<u>AB</u>		<u>EQ 4MG BASE</u>	<u>A211397</u>	<u>002</u>	Oct 26, 2018
<u>AB</u>	ZYDUS PHARMS	<u>EQ 2MG BASE</u>	<u>A208884</u>	<u>001</u>	Oct 22, 2020
<u>AB</u>		<u>EQ 4MG BASE</u>	<u>A208884</u>	<u>002</u>	Oct 22, 2020

ALBUTEROL SULFATE; BUDESONIDE

AEROSOL, METERED; INHALATION

AIRSUPRA

+	!	ASTRAZENECA	EQ 90MCG BASE/INH; 80MCG/INH	N214070	001	Jan 10, 2023
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ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

<u>AN</u>	CIPLA	<u>EQ 0.083% BASE;0.017%</u>	<u>A077559</u>	<u>001</u>	Dec 31, 2007
<u>AN</u>	! NEPHRON	<u>EQ 0.083% BASE;0.017%</u>	<u>A076749</u>	<u>001</u>	Dec 31, 2007
<u>AN</u>	RITEDOSE CORP	<u>EQ 0.083% BASE;0.017%</u>	<u>A202496</u>	<u>001</u>	Oct 01, 2012
<u>AN</u>	SUN PHARM	<u>EQ 0.083% BASE;0.017%</u>	<u>A207875</u>	<u>001</u>	Aug 07, 2017

SPRAY, METERED; INHALATION

COMBIVENT RESPIMAT

+	!	BOEHRINGER INGELHEIM	EQ 0.1MG BASE/INH; 0.02MG/INH	N021747	001	Oct 07, 2011
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ALCLOMETASONE DIPROPIONATE

CREAM; TOPICAL

ALCLOMETASONE DIPROPIONATE

<u>AB</u>	!	FOUGERA PHARMS	<u>0.05%</u>	<u>A076973</u>	<u>001</u>	Jul 12, 2005
<u>AB</u>		GLENMARK GENERICS	<u>0.05%</u>	<u>A079061</u>	<u>001</u>	Jun 23, 2009
<u>AB</u>		TARO	<u>0.05%</u>	<u>A076587</u>	<u>001</u>	Sep 15, 2005

OINTMENT; TOPICAL

ALCLOMETASONE DIPROPIONATE

<u>AB</u>	!	FOUGERA PHARMS	<u>0.05%</u>	<u>A076884</u>	<u>001</u>	Jul 18, 2005
<u>AB</u>		GLENMARK GENERICS	<u>0.05%</u>	<u>A079227</u>	<u>001</u>	Jul 30, 2009
<u>AB</u>		TARO	<u>0.05%</u>	<u>A076730</u>	<u>001</u>	Jul 29, 2004

ALCOHOL

SOLUTION; INTRA-ARTERIAL

ABLYSINOL

+		BPI LABS	99% (1ML)	N207987	001	Jun 21, 2018
+	!		99% (5ML)	N207987	002	Jun 21, 2018

ALECTINIB HYDROCHLORIDE

CAPSULE; ORAL

ALECENSA

+	!	HOFFMANN-LA ROCHE	EQ 150MG BASE	N208434	001	Dec 11, 2015
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ALENDRONATE SODIUM

SOLUTION; ORAL

ALENDRONATE SODIUM

<u>AA</u>	!	HIKMA	<u>EQ 70MG BASE/75ML</u>	<u>A090520</u>	<u>001</u>	Feb 25, 2013
<u>AA</u>		NOVITIUM PHARMA	<u>EQ 70MG BASE/75ML</u>	<u>A214512</u>	<u>001</u>	May 11, 2023

TABLET; ORAL

ALENDRONATE SODIUM

<u>AB</u>	APOTEX	<u>EQ 5MG BASE</u>	<u>A077982</u>	<u>001</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 10MG BASE</u>	<u>A077982</u>	<u>002</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 35MG BASE</u>	<u>A077982</u>	<u>003</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 70MG BASE</u>	<u>A077982</u>	<u>004</u>	Aug 04, 2008
<u>AB</u>	AUROBINDO PHARMA	<u>EQ 10MG BASE</u>	<u>A090124</u>	<u>001</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 35MG BASE</u>	<u>A090124</u>	<u>002</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 70MG BASE</u>	<u>A090124</u>	<u>003</u>	Aug 04, 2008
<u>AB</u>	CIPLA	<u>EQ 5MG BASE</u>	<u>A076768</u>	<u>001</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 10MG BASE</u>	<u>A076768</u>	<u>002</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 35MG BASE</u>	<u>A076768</u>	<u>003</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 40MG BASE</u>	<u>A076768</u>	<u>004</u>	Aug 04, 2008
<u>AB</u>		<u>EQ 70MG BASE</u>	<u>A076768</u>	<u>005</u>	Aug 04, 2008
<u>AB</u>	HANGZHOU BINJIANG	<u>EQ 5MG BASE</u>	<u>A090258</u>	<u>001</u>	Sep 24, 2009
<u>AB</u>		<u>EQ 10MG BASE</u>	<u>A090258</u>	<u>002</u>	Sep 24, 2009

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APPENDIX C**UNIFORM TERMS*****DOSAGE FORMS***

AEROSOL, FOAM	PASTE
AEROSOL, METERED	PATCH
CAPSULE	PELLET
CAPSULE, DELAYED REL PELLETS	PELLETS
CAPSULE, DELAYED RELEASE	POWDER
CAPSULE, EXTENDED RELEASE	POWDER, EXTENDED RELEASE
CAPSULE, PELLETS	POWDER, METERED
CAPSULE, TABLET	RING
CAPSULE, TABLET, TABLET	SHAMPOO
CLOTH	SOLUTION
CONCENTRATE	SOLUTION FOR SLUSH
CREAM	SOLUTION, EXTENDED RELEASE
CREAM, AUGMENTED	SOLUTION, GEL FORMING/DROPS
CREAM, INSERT	SOLUTION, METERED
ELIXIR	SOLUTION/DROPS
EMULSION	SPONGE
ENEMA	SPRAY
FILM	SPRAY, METERED
FILM, EXTENDED RELEASE	SUPPOSITORY
FOAM	SUSPENSION
FOR SOLUTION	SUSPENSION, EXTENDED RELEASE
FOR SUSPENSION	SUSPENSION, LIPOSOMAL
FOR SUSPENSION, DELAYED RELEASE	SUSPENSION/DROPS
FOR SUSPENSION, EXTENDED RELEASE	SWAB
GAS	SYRUP
GEL	SYSTEM
GEL, AUGMENTED	TABLET
GEL, METERED	TABLET, CHEWABLE
GRANULE	TABLET, DELAYED RELEASE
GRANULE, DELAYED RELEASE	TABLET, EFFERVESCENT
GRANULES	TABLET, EXTENDED RELEASE
GRANULES, EXTENDED RELEASE	TABLET, EXTENDED RELEASE,
GUM, CHEWING	CHEWABLE
IMPLANT	TABLET, FOR SUSPENSION
INHALANT	TABLET, ORALLY DISINTEGRATING
INJECTABLE	TABLET, ORALLY DISINTEGRATING,
INJECTABLE, LIPID COMPLEX	DELAYED RELEASE
INJECTABLE, LIPOSOMAL	TABLET, ORALLY DISINTEGRATING,
INJECTION, EXTENDED RELEASE	EXTENDED RELEASE
INSERT	TAPE
INSERT, EXTENDED RELEASE	TROCHE/LOZENGE
INTRAUTERINE DEVICE	
JELLY	
LIQUID	
LOTION	
LOTION, AUGMENTED	
LOTION/SHAMPOO	
OIL	
OIL/DROPS	
OINTMENT	
OINTMENT, AUGMENTED	

Note: Terms comprise currently marketed products

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APPENDIX C**UNIFORM TERMS*****ROUTES OF ADMINISTRATION***

BUCCAL	N/A
CARDIAC	NASAL
DENTAL	OPHTHALMIC
ENDOCERVICAL	ORAL
ENDOTRACHEAL	ORAL-21
ENTERAL	ORAL-28
IMPLANTATION	OTIC
INFILTRATION	PERFUSION
INHALATION	PERIARTICULAR
INJECTION	PERIODONTAL
INTERSTITIAL	PYELOCALYCEAL
INTRA-ANAL	RECTAL
INTRA-ARTERIAL	SPINAL
INTRA-ARTICULAR	SUBCUTANEOUS
INTRACAMERAL	SUBLINGUAL
INTRACAVITARY	TOPICAL
INTRACRANIAL	TRANSDERMAL
INTRADERMAL	TRANSMUCOSAL
INTRAMUSCULAR	URETHRAL
INTRAOCULAR	VAGINAL
INTRAOSSEOUS	
INTRAPERITONEAL	
INTRAPLEURAL	
INTRATHECAL	
INTRAUTERINE	
INTRAVENOUS	
INTRAVESICAL	
INTRAVITREAL	
IRRIGATION	
IV (INFUSION)	

Note: Terms comprise currently marketed products

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APPENDIX C**UNIFORM TERMS*****ABBREVIATIONS***

AMP	AMPULE
AMPICIL	AMPICILLIN
APPROX	APPROXIMATELY
BOT	BOTTLE
CI	CURIE
CSR	CAROTID SINUS REFLEX
CU	CLINICAL UNITS
DIPROP	DIPROPIONATE
ELECT	ELECTROLYTE
EQ	EQUIVALENT TO
ER	EXTENDED RELEASE
GM	GRAM
HBR	HYDROBROMIDE
HCL	HYDROCHLORIDE
HR	HOURLY
IM	INTRAMUSCULAR
INH	INHALATION
IU	INTERNATIONAL UNITS
IV	INTRAVENOUS
KIU	KALLIKREIN INHIBITOR UNITS
MCG	MICROGRAM
MCI	MILLICURIE
MEQ	MILLIEQUIVALENT
MG	MILLIGRAM
ML	MILLILITER
N/A	NOT APPLICABLE
PPM	PARTS PER MILLION
REL	RELEASE
SC	SUBCUTANEOUS
SQ CM	SQUARE CENTIMETER
U	UNITS
UCI	MICROCURIE
UMOLAR	MICROMOLAR
USP	UNITED STATES PHARMACOPEIA